

## Maxi-Vac 1.0

Draft: Beta Test Version, December 2002

Software and manual to help state and local-level public health officials plan for setting up smallpox vaccination clinics.

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#### Introduction

The World Health Organization formally declared the eradication of smallpox on May 8, 1980. Following this major public health accomplishment, smallpox vaccinations were ceased throughout the world. As a result of the cessation of vaccination, millions of Americans and people around the world have no immunity to the smallpox virus. Although the last recorded natural case of smallpox occurred in 1977, the intentional release of the smallpox virus has emerged as a potentially devastating bioterrorism threat. Given the vulnerability of the world population to smallpox, such an attack could have devastating consequences.

To help states and local communities prepare to respond to a smallpox attack should one occur, the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services has released generic guidelines on how to set-up a smallpox vaccination clinic (see <a href="www.cdc.gov/agent/smallpox/response-plan/index.asp">www.cdc.gov/agent/smallpox/response-plan/index.asp</a> to view the plan). However, individual states and communities have differing numbers of qualified personnel that would be available in such an event.

#### Overview of Maxi-Vac

Maxi-Vac helps a public health official answer the following question: "How can I allocate the limited number of personnel available so that the maximum number of people are vaccinated in a 24 hour period?"

Maxi-vac was developed by first building a computer model using both Arena® simulation software (version 5.0, Rockwell Software, Inc. Sewickley, PA) and an add-on optimization program (OptQuest®, version 5.0, OptTek Systems, Inc., Boulder, CO). The objective of the mathematical model was to allocate personnel such that a maximum number of people could be vaccinated in a clinic during a 24 hour-period. Built into the model was the stipulation that the average time spent in the clinic by the patients was less than or equal to 90 minutes. The data generated by each run of the model is stored in Maxi-Vac's database. Based on your inputs (e.g., the number of personnel available for each shift in a clinic), the appropriate set of data is accessed in the database and displayed in the "Results" section of Maxi-Vac. Technical details on the underlying assumptions used in Maxi-Vac are provided in the Appendix of this manual.

## **Description of the Simulation Model**

A smallpox vaccination clinic consists of a number of "stations," or activities, that a patient may "visit." The actual number of stations that a given patient "visits" will depend upon that patient's personal circumstance (e.g., history of a possible pre-existing medical condition indicating that they should not be vaccinated unless exposed to somebody who was infectious) and the actual requirements for giving smallpox vaccinations. Clinic personnel must of course, staff each station. The stations, or activities are:

• <u>Triage</u>: Before patients enter the clinic they go through a triage point where they are triaged by a medical provider for illness and/or to determine whether they have been in contact with confirmed cases of smallpox. This checkpoint is to screen out those individuals that may be ill or who may be contacts from the rest of the individuals at the clinic so as not to expose the clinic population. Examples of persons who will not be treated in the clinic after being triaged are those are ill and therefore require treatment at another site, and those that are identified as contacts.

- Orientation: Individuals will view a video that contain a variety of information, such as care of the vaccination site, possible side-effect, when and how to seek treatment for such side effects, and (where necessary) the essential elements of informed consent as promulgated in 21 CFR 50.25.
- <u>Medical Forms</u>: All individuals (contacts and mainstream) will receive an information packet that will include medical screening and consent forms (where necessary) to be filled out for each family member.
- <u>Referral</u>: The completed medical screening forms mentioned above will be reviewed by non-medical personnel to see if the patients have self-reported any history of a possible pre-existing medical condition indicating that they should not be vaccinated unless exposed to somebody who was infectious (contraindications). Patients with potential contraindications will then proceed to the medical screening area; all others go directly to the vaccination area.
- Medical Screening: Patients who self-reported contraindicating conditions on their screening forms will receive screening and information from a medical professional. If the person conducting the screening is uncertain, or the patient wishes more information, that patient will be referred for additional screening to a qualified physician.
- **Physician Evaluation:** Patients with self-reported contraindicating conditions receive a more detailed screening if deemed necessary by the medical screener.
- <u>Vaccination/Witness:</u> Patients receive their smallpox vaccinations from an approved medical provider. A second medical provider acts as witness. To limit fatigue, the medical providers can, during the course of their shift, switch occupations.
- <u>Exit Review</u>: This is the final station in the clinic. Patients can have any remaining questions answered, and the personnel staffing this station can ensure that each patient exits with their information sheets and instructions.

#### Data sources

Much of the data required to run this model are not readily available. Your health department will need to research to find data such as the number of health care providers, number of support staff, etc. Where appropriate, we have included a list of suggested data sources that may help you in this process.

## Modeling philosophy: Sensitivity analyses and overall objectives

Much of the input data required for the model is unknown. The values used in the model are therefore mostly based on expert opinion. Even those data may not be reliable predictors of the process times and staff that will be required to engage in large-scale mass smallpox vaccinations. Therefore, we encourage you to be realistic when interpreting the results obtained from this software.

Given this uncertainty, we also encourage you to run the model several times. Once you have become adept at using the software, you may wish to consider a plan wherein you systematically alter the values of input variables. You may alter one variable at a time (univariate sensitivity analysis), or alter the values of two or more variables simultaneously (multivariate sensitivity analysis). Different results due to using different values for the various input variables will help you obtain a sense of the relative importance of each staff type in determining the number of people that can be treated in a 24-hour period. We have included in the results the impact of adding or removing one of each type of staff, which again, will give you a sense of the relative importance of increasing or decreasing staff at a specific station.

#### Disclaimer

Please keep in mind that this is a **test** version of the software and a **draft** version of the manual. The numbers generated through use of the software should not be considered predictions of what will definitely occur whilst running a mass immunization clinic. Rather, they are estimates of what could happen.

## Help and feedback

For help using Maxi-Vac and/or interpreting the results, please e-mail your questions to Dr. Martin Meltzer at qzm4@cdc.gov. Please note that we are not commercial developers of software, and we ask for your patience if it takes us some time to reply to your requests.

We also would appreciate any comments and suggestions as to how we could improve the software. For example, we would be interested in receiving suggestions for additional input/ output screens. What other data regarding impact would you like to see included in the software?

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## **System Requirements**

This software (Maxi-Vac 1.0) requires an IBM-compatible computer system that runs on MS Windows95\* (or higher). We recommend that the IBM-compatible computer have at least a 486 or Pentium microprocessor chip. Since Maxi-Vac requires the use of Windows95, we recommend that the computer have at least 128MB of installed RAM.

**NOTE:** Maxi-Vac requires up to **1.4 megabytes** of storage space on the computer's hard drive.

\*Windows95 is a copyrighted product produced by Microsoft Corporation, WA. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

## **Installing Maxi-Vac**

The Maxi-Vac application may be installed from the Internet.

#### To install from the Internet:

Use your internet browser to login to the Maxi-Vac web site. The following download options will be presented:

VBRun60sp5.exe - If you do not already have the Visual Basic 6.0 run-time files installed in your computer, you must then download and execute the file VBRun60sp5.exe. This is a self-extracting executable file that installs the latest versions of the Microsoft Visual Basic run-time files required by all applications created with Visual Basic 6.0.

Note: The files include the fixes shipped with Visual Studio 6.0 Service Pack 5.

**Maxi-Vac application** - This is the actual Maxi-Vac installation module. You must already have the Visual Basic 6.0 run-time files installed in your computer in order to install and run the Maxi-Vac application. Download the Maxi-Vac install file to a directory in your hard drive and double-click on the downloaded file to commence the installation.

## **Common Buttons and Menu Items**



The following buttons are found on every screen of the software:



This button allows you to run a new scenario, starting from the beginning. You will be asked if you want to save your previous scenario and results to a file. To do so, select "Yes" and provide a name and location for the saved file. If you do not wish to save the previous scenario and results, select "No".



This button allows you to select a previously run scenario. A screen will open showing all files in the folder you last used to save a scenario. Click on or type in the name of the file you wish to use, then click on the "Open" button shown on the screen. Inputs and results in this file will be restored in MaxiVac.



This button allows you to save the inputs and results from the current scenario. You will be asked to name the file and indicate the location of the file. You can later select this named file by clicking on the "Open" button. Be sure to save your inputs and results before closing the application, if you do not wish to loose the current scenario and results.



The print button allows you to print an output report of the current scenario and results. The print button is only active when you are in the "See Results" section.



By clicking on this button, you will get additional information that is related to the current screen.



This button will display the authors' contact information in the event you would like to send a feedback or have a question that was not addressed in the current manual

The following tabs are available on every page of the software:

Enter Personnel | Enter Activities | Enter % of Families | Scenario Summary | See Results |

**Enter Personnel** This tab takes you to the screen where you selected the number

of staff in each category: physicians, other medical professionals,

and support staff.

Enter % of Families This tab takes you to the screen where, in future versions, you

can select the proportion of families that fall in each of the

categories displayed.

**Scenario Summary** This tab offers you a visual of display of all of the inputs you

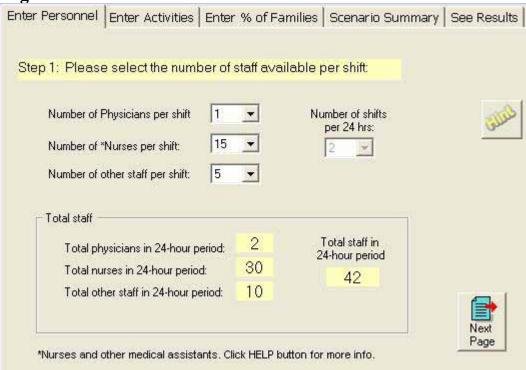
selected for your review.

**Results** This tab takes you to the "Results" page. On the "Results" page,

you can go to the desired page by selecting the appropriate tab. The following tabs are available on the "Results" page: People Treated; Staff Utilization; Impact/Minus One; Impact/Plus One; and Average Time Spent. For detailed descriptions on the screens associated with each of these tabs, please refer to the

appropriate section in this manual.

**Page 1: Enter Personnel** 

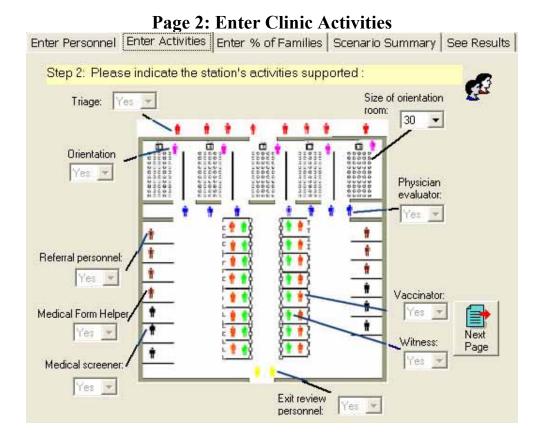


This page allows you to enter input values for the number of each staff type and the number of shifts to be worked during a 24-hour period.

- Number of each type of staff available to work on each shift: Select the total number of physicians, other medical staff, and non-medical support staff estimated to be available to work each shift at the vaccination center from the pull-down menu under each category.
- Number of shifts in a 24-hour period: Select whether the clinic staff will work in two12-hour shifts or three 8-hour shifts. Note: In Maxi-Vac version 1.0, the only (default) value is 2 shifts per 24-hour period. The assumption can be made that each shift will only run for 8 hours (i.e., clinic will be open 16 hours per 24 hour period). The clinic director may need to adjust the length of each shift to allow for changes in patient arrivals and the actual amount of time in the clinic taken by a "typical" patient.

Note: You may want to obtain composite estimates of the number of personnel available to work at the clinics from appropriate sources such as local/regional health departments, state licensing organizations, hospitals, professional societies, support organizations (e.g. Red Cross), etc. Reasonable estimates of the number of staff at any particular locations will be constrained by the number of staff available and the physical space in which the clinic will be setup.

**HINT:** Note that the term "Nurses" refers to any medically-trained staff (other than physicians) who are qualified to work in the clinic—EMTs, for example.



Enter the activities that will be included in your clinic on this screen. Certain activities (e.g. Triage, Referral, Vaccinations) must be included and cannot be set to "No". The default value for all stations is "Yes", but for those stations that can be omitted in the clinic design, you may select the "No" options. In addition to the stations that will be used in the clinic, you must select the number of people that each orientation session can hold (i.e. 30 or 75 people). Please see the Appendix for additional technical details.

In Version 1.0, all stations must be included; therefore "Yes" is shown for all values in Step 2. You can, however, select the number of people that each orientation room can hold per session.

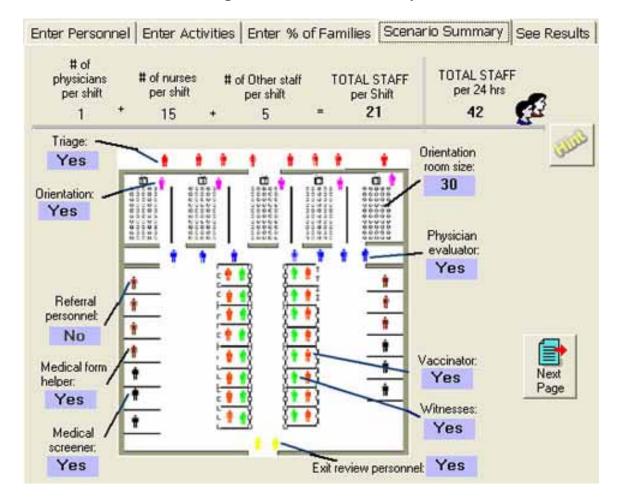
**Page 3: Enter Percents of Families Affected** 

Enter Personnel	Enter Activities	Enter % of	Families	Scenario Summ	ary   See Results
	e following perc in this version (1				
	will allow you to	AND DESCRIPTION OF THE PERSON	THE REPORT OF THE PARTY OF		
		140000000000000000000000000000000000000			
Percen	tage of families turne	ed away at triag	je:	2% 💌	
Percen	tage of families that i	need to be trea	ated elsewhe	re: 2% 🛩	
Percen	tage of families sent	to medical scr	eener:	10% 🕶	
Percen	tage of families to se	e physician ev	aluator:	10% 🔻	
				200	

Select the percentage of families falling in the following categories:

- Percentage of families turned away at triage: This is the percent of the total population where at least one family member is either sufficiently ill or shows symptoms of smallpox and therefore requires treatment at another site. If a family member does show possible symptoms of smallpox (or, perhaps, self-identifies as having been in lose contact with a known smallpox victim) then it is quite likely that the entire family will be moved to another site for a medical exam, vaccination and perhaps quarantine (as appropriate).
- **Percentage of families that need to be treated elsewhere:** This is the percent of the total population where the physician evaluator determines that at least one family member requires treatment at another site.
- **Percentage of families to see a medical screener:** This is the percent of the total population where at least one family member has a condition noted on the screening form that should be reviewed by a medical professional such as a nurse or EMT.
- Percentage of families to see a physician evaluator: This is the percent of the total population where at least one family member has a potentially serious contraindication that can best be determined by a physician.

**HINT:** You may want to experiment with how changing these values affects the number of staff allocated at each station and the number of people that can be vaccinated in a 24-hour period. **This option is not available in Version 1.0.** 



Page 4: Scenario Summary

This screen displays your selections for the setup of the smallpox vaccination for your review. You may make changes to your inputs by clicking on the appropriate tab, e.g. "Enter Personnel". If there are no changes to be made, proceed to the next screen by clicking on the "Next Page" button or the "See Results" tab. Note that in Version 1.0, all activities (stations) are fixed at "Yes", however future versions may allow you to exclude certain activities.

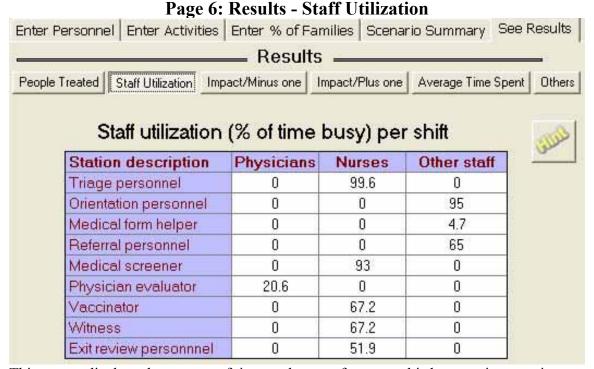
**HINT:** You may want make multiple runs to see how removing one or more optional stations affects the results. **This option is not available in Version 1.0.** 

Page 5: Results – Number of People Vaccinated and Optimal Staff Allocation

	Result	s <u> </u>		
le Treated Staff Utilization Ir	mpact/Minus one	act/Minus one   Impact/Plus one   A		nt Ot
Total r	number of staff avai	lable per shift:	21	
Ac	tual number of staff	21	(II)	
Maximum number of people that can be treated in a 24-hour period: 3310				
Station description	Physicians	12.27	Other staff	
Triage personnel	0	3	0	
The second secon		12.27		
Triage personnel	0	3	0	
Triage personnel Orientation personnel	0	3	0	
Triage personnel Orientation personnel Medical form helper	0 0	3 0 0	0 2 1	
Triage personnel Orientation personnel Medical form helper Referral personnel	0 0 0	3 0 0	0 2 1 2	
Triage personnel Orientation personnel Medical form helper Referral personnel Medical screener	0 0 0	3 0 0 0 0 2	0 2 1 2 0	
Triage personnel Orientation personnel Medical form helper Referral personnel Medical screener Physician evaluator	0 0 0 0 0	3 0 0 0 2 0	0 2 1 2 0 0	
Triage personnel Orientation personnel Medical form helper Referral personnel Medical screener Physician evaluator Vaccinator	0 0 0 0 0 0	3 0 0 0 2 0 4	0 2 1 2 0 0	

This screen displays the results from the simulation and optimization runs based on the inputs you chose. The top two boxes show the number of total staff available and total staff used. The third box presents the maximum number of people that can be vaccinated at the clinic using the staff as shown in the table, based on the model assumptions. (The model assumptions are presented in the technical appendix of this manual). You should be aware that the results might be significantly different for another set of model assumptions. The table displays the number of specific types of personnel needed at each station. When a particular staff type is not used at a station, "NA" is shown in the table. If the total number of people that can be treated is too low, you may be able to increase patient flow by adding additional staff. Reviewing the "Impact" results will provide some insights into the potential benefit of adding or removing 1 staff person at specific stations.

**HINT:** The placement of specific staff types at each station is based on recommendations made by medical professionals familiar with mass vaccination procedures. You should determine whether there are any difference between the suggested type of personnel at each station and those called for in your community's smallpox response plan.

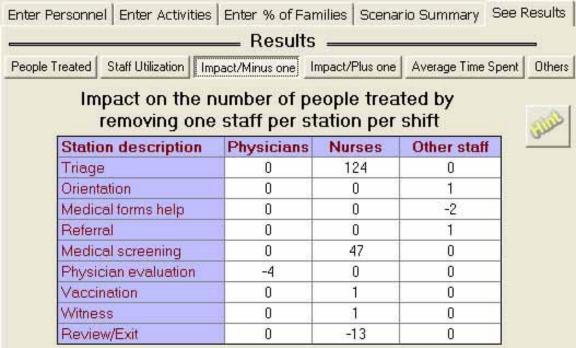


This screen displays the percent of time each type of personnel is busy seeing a patient during his or her shift. When a particular staff type is not used at a station, "NA" for 'not applicable' is displayed in the table.

In general, you want the system to be "balanced" so that the majority of staff is kept sufficiently busy, but are not working at a pace that cannot be sustained throughout their shift. Keep in mind that the tool (Version 1.0) does not consider staff breaks of any type. To account for breaks, additional staff will be required to relieve workers. Also note that staff utilizations may be low at stations where only a percentage of people are seen (e.g. physician evaluation) if the percentage of people requiring service at that station is low enough. However, low utilizations may be indications of having more staff than are needed at the affected stations. Also note that low utilizations do not necessarily correspond to short patient wait times.

**HINT:** Utilization is the amount of time that an individual spends actively working. For example, a utilization of 100% corresponds to a person who works non-stop (no breaks of any kind) for the entire shift. You might consider having additional personnel to provide relief for staff who are busy more than 80% of the time, and/or having these staff work fewer hours.

Page 7: Results - Impact of Removing One Person at Each Station

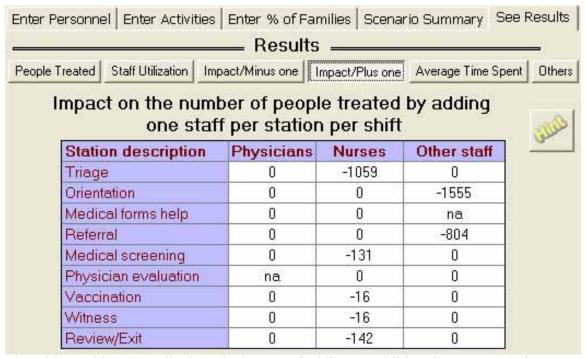


The table on this screen displays the impact of removing one person at each station where the optimum allocation of staff is greater than 1. For stations where the optimal allocation is 1, "na" is shown in the table to indicate that it was inappropriate to reduce the number of staff at these stations. The values shown in the table are the differences between the maximum number of people that can be vaccinated if the clinic is fully staffed based on results for your specific inputs and the number that can be treated if the optimal number of staff at that specific station is decreased by one. Small changes in the number of people treated, say differences of around 10% or less, are not of interest here. What is of interest is when a reduction in the number of staff at a station by 1 results in a substantial decrease in the number of people that can be vaccinated in 24 hours. The size of the decrease (or increase) is related to the relative importance of having sufficient personnel at a particular station. In general, it is important to have a sufficient number of staff for those stations through which the majority of people must pass (e.g. triage, orientation, etc). When a particular staff type is not used at a station, "NA" for 'not applicable' is displayed in the table. You should note that small increases (or decreases) in the number of people vaccinated when the number of staff at a particular station is decreased are not practically significant.

**HINT:** Small increases (or decreases) in the number of people vaccinated when the number of staff at a particular station is decreased are not practically significant.

Due to the time associated with running each combination of inputs long enough to obtain the "true" optimal allocation of resources given the constraints inputted, it may be possible that there are other arrangements that might result in more people vaccinated than is shown on "People Treated" tab of the Results file. You might be tempted to use the Impact Results to find a "better" arrangement. For example, if the combined results of adding and removing staff suggests that moving one or more persons from one position (say medical screening) to another position for which she/he is qualified to work (say triage), it might be possible to treat more people. However, such an arrangement might not satisfy one or more of the constraints (e.g. patient time in the clinic  $\leq 90$  minutes; see "Model Assumptions" in the Technical Appendix), therefore caution must be used in attempting to combine the impact of adding and removing staff.

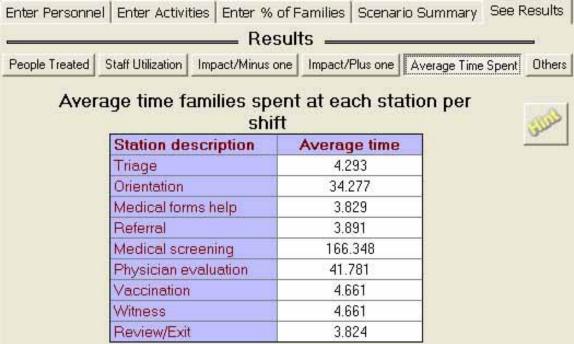
Page 8: Results - Impact of Adding One Person at Each Station



The table on this screen displays the impact of adding an additional person at each station. The values shown in the table are the differences between the number that can be treated if the optimal number of staff at that specific station is increased by one and the number of people that can be vaccinated if the clinic is fully staffed based on results for your specific inputs. The size of the increase (or decrease) is an indication of the relative benefit (or cost) of adding an additional person at a particular station. In general, there will be little benefit in adding additional staff at any one station because the allocation of staff has already been optimized. When a particular type of staff is not used at a station, "NA" is displayed in the table.

**HINT:** Small increases (or decreases) in the number of people vaccinated when the number of staff at a particular station is increased are not practically significant.





This screen shows the average amount of time patients spend at each station. In general, longer times indicate either a process that requires a significant amount of time (e.g. orientation) or a bottleneck in the system. Whereas orientations represent an unavoidable bottleneck (because they do not start until there are enough people waiting inside the orientation room – an input value), bottlenecks at other stations may result because of the time it takes for the service to be administered and/or the sheer volume of people that must be seen at a specific station (e.g. triage, clerk). The size of these bottlenecks will greatly depend on the number of personnel available to work at the affected station(s).

Often there are tradeoffs to be made when there is a limited number of each staff available to work in the clinic. For example, medical professionals (other than physicians) staff 5 of the 9 stations in this model: triage, medical screening, vaccination/witness and exit review. In order to move the maximum number of people through the clinic, it is important to allocate a sufficient number of medical staff to work at these stations since all patients that come to the clinic must go through these stations. Consequently, the number of staff allocated to these stations must be "balanced" to allow for patients to move through the clinic at the maximum rate possible given the input constraints (see the technical appendix for a list of constraints used).

**HINT:** Average times shown on this screen includes processing time at the station plus the time spent waiting in the queue for service. Times spent in the clinic do not include any waiting time experienced before entering the clinic or station-to-station transit time.

Enter Personnel   Enter Activities   E	sults – Other Support Staff Enter % of Families   Scenario Sum – Results –	
People Treated   Staff Utilization   Impac	ct/Minus one   Impact/Plus one   Avera	ge Time Spent Others
Breakdown of other o	linic personnel per shift	
Position	Number per shift	all the
Form distribution	9	935
Vaccine preparation	2	
Medical records data	10	
Clinic manager	2	
Supply manager	2	
Clinic QA reviewer	4	
Security	20	
Traffic flow	2	
Translator	1 (per major language)	
Float staff	3	
Contact evaluation	4	
EMT	1	
IT support	1	
Tota	<b>l</b> 61	

This screen shows estimates of the number of various types of clinic support staff. These are the suggested values given in the CDC Smallpox Response Plans and Guidelines (Version 3.0), Annex 3. Please be aware that the numbers of staff and the activities included in this table have not been optimized.

HINT: This table contains suggested numbers of various types of personnel based on approximately 5000 people being treated as contained in the CDC Smallpox Response and Guidance Plan (Version 3.0), Annex 3. To our knowledge, no actual data exists to corroborate these suggested values – the values are based on expert opinion. As such, clinic planners may wish to increase (or decrease) the numbers of "Other Clinic Personnel" as they deem needed.

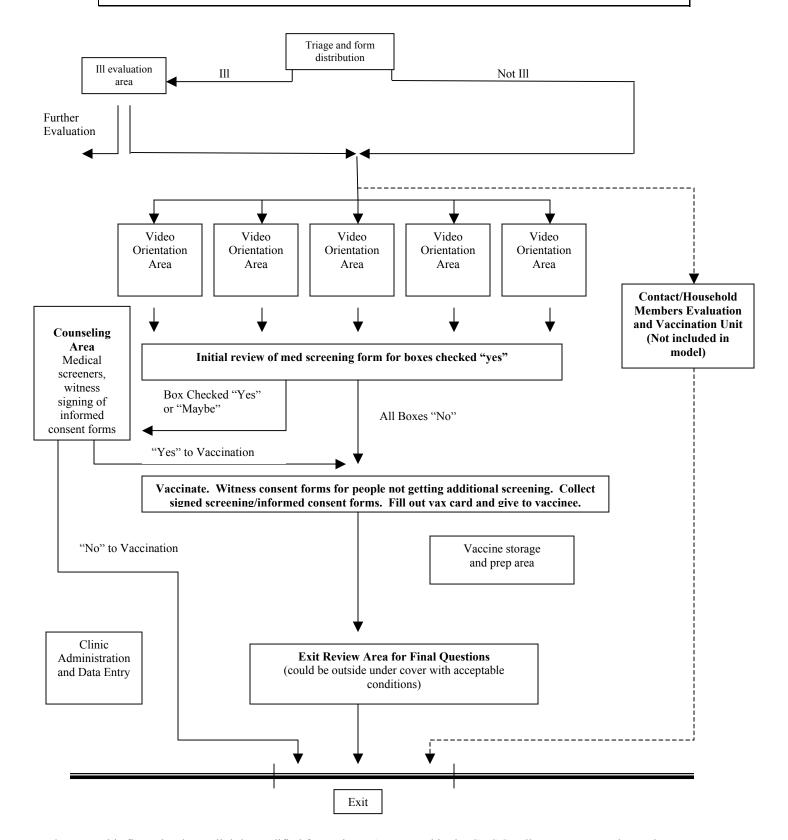
## **Technical Appendix**

## **Model Assumptions**

The following assumptions were used to develop the current version of the simulation model:

- 1. Each scenario is run for a period covering 24 hours.
- 2. One average, patients spend no more than 90 minutes in the clinic (constraint).
- 3. An unlimited number of people are outside of the dispensing center waiting for treatment at all times—a worst-case scenario.
- 4. All family members move together through the dispensing center.
- 5. All family members have the same level of potential exposure.
- 6. Sufficient resources are available to keep each station fully staffed and functioning at 100% efficiency during the 24 hours.
- 7. A linear relationship exists between mean provider service time and the number of people in a family.
- 8. A maximum of 5 orientation rooms will be set up at each vaccination clinic (constraint).
- 9. Patient transit times between stations are not included in the model.

# FIG. 1 SCHEMATA OF MODEL VACCINATION CLINIC\*



<sup>\*</sup>Note – This figure has been slightly modified from Figure 1 presented in the CDC Smallpox Response Plan and Guidelines (Version 3.0). Annex 3.

#### **Input Probabilities\***

Percent of families in which all have previously been vaccinated*	2
Percent symptomatic/contact (exit clinic); these families exit the	
clinic after being triaged	
Percent identified as not treatable at the clinic site; these families exit	2
the clinic after being triaged	
Percent of people who need help with filling out their	2
medical/consent forms	
Percent with complicating health factors; these families require	10
additional medical screening beyond that given at the referral station	
Percent with complicating health factors that are identified by the	10
medical screener and who are not treatable on site; these families will	
exit the clinic after seeing a medical screener and will exit the clinic	
before receiving a vaccination	
Percent with complicating health factors that are identified by the	5
physician evaluator and who are not treatable on site; these families	
will exit the clinic after seeing the physician evaluator and will exit	
the clinic before receiving a vaccination	

**Note:** These are assumed values only. The current version of the model assumes that even if a single member of a family meets a given criteria (e.g., at triage sent to another site for treatment), then the entire family will accompany that one person.

\* Previously vaccinated during current vaccination campaign, such as at another clinic. The term "previously vaccinated" does not include those vaccinated, say, 30 years ago.

## **Input Distributions\***

Process	Distribution	Minimum, Most
		Likely, Maximum
		(minutes)
Triage (per family member)	Triangular	(0.5, 1.0, 2)
Orientation	Triangular	(20, 25,30)
Fill-out forms w/o help (per family member)	Triangular	(0.5, 1.0, 1.5)
Fill-out forms w/ help (per family member)	Triangular	(0.3, 1.0, 1.5)
Referral (per family member)	Triangular	(0.4, 0.5, 0.75)
Medical screening (per family member)	Triangular	(5, 10, 15)
Physician evaluation	Triangular	(5, 10, 15)
Exit review (per family member)	Triangular	(2, 3, 5)
Vaccination (per family member)	Triangular	(0.5, 1, 1.5)

**Note:** The values in this table may differ from those given in the CDC Smallpox Response Plans and Guidelines (Version 3.0), Annex 3. These values may change in later versions if and when additional new data become available.